UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,994	11/06/2001	Victor Raso	BBRI-2005	1367

7590 02/24/2004

Kevin M. Farrell
Kevin M. Farrell, P.C.
ONE NEW HAMPSHIRE AVENUE
SUITE 350
PORTSMOUTH, NH 03801

EXAMINER	
PATTERSON, CHARLES L JR	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/992,994	RASO, VICTOR	
	Examiner	Art Unit	
	Charles L. Patterson, Jr.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-82 and 84* is/are pending in the application.

4a) Of the above claim(s) *60-63,79-82 and 84* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-59 and 64-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 November 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 60-63, 79-82 and 84 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

It is pointed out that applicant has not replied to the PTO-948 mailed 11/17/03. Drawing corrections may no longer be held in abeyance.

The previous objection to the specification for not containing a reference to the continuity is hereby dropped. Applicant provided this information in the Application Data Sheet. After further consideration of the claims and specification, the following non-final rejection is deemed appropriate.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a combination written description and enablement rejection.

The specification teaches that Aβ antigens can be used to produce anti-Aβ antibodies in mice. It is teaches that anti-Aβ antibodies can be produced in Cynomolgus monkeys. The specification does not teach that β-amyloid epitopes can be used to inhibit the formation of β-amyloid plagues and aggregates in the brain of humans. Although it is maintained by applicant that the Cynomologus monkey system "is highly relevant to human applications since the predicted amino acid sequence of β-amyloid in these primates is identical to humans, and their basic physiology and immunological systems closely approximate those which will be encountered in a clinical situation" (page 30, lines 17-21), the only thing that the specification shows is that anti-Aβ antibodies can be made in this system using Aβ as an antigen, not that they can be used to inhibit the formation of β-amyloid plagues and aggregates in the brain of these monkeys. Therefore it is maintained that applicant was not in possession of the claimed invention at the time the application was filed and furthermore that applicant does not teach one of ordinary skill in the art how to make and/or use the claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 64 and 76-78 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki, et al. (A). This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

Applicant states that they have changed the recitation to "human compatible adjuvant" and that Freund's adjuvant taught in the instant reference is too reactive to be used in humans, citing Vogel, et al. (U). Although the reference states that "Complete Freund's adjuvant (CFA) is...too reactive to be used clinically..., incomplete Freund's adjuvant (IFA)...has been used in several vaccine formulations...and has been administered to more than a million people". Suzuki, et al. states in column 15, lines 46-47 that "Freund's complete adjuvant or Freund's incomplete adjuvant" was used. Therefore the instant amendment does not affect the instant rejection.

Claims 64-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki, et al. This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection. The Anderson reference has been dropped.

Applicant argues that the reference "teaches away from the use of human-compatible adjuvant...[and since] the relevant teaching of the cited reference only relates to the production of monoclonal antibodies...[that] requires the sacrifice of the immunized animal", the reference teaches away from the claims. The examiner does not agree. The instant claims require only "a hu-

man compatible adjuvant formulation" not the production of antibodies in humans. It is maintained that all of the other requirements of the instant claims are well known to one of ordinary skill in the art and/or would have been obvious, absent a convincing showing to the contrary.

Claims 37-59 and 64-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schenk (AL). The instant reference teaches that antibodies produced using $A\beta_{42}$ as immunogen in mice reduced the cortical amyloid burden, reduced formation of Aβ deposits (pages 41-48), and the "$A\beta_{1-42}$ injections are highly effective in the prevention or deposition or clearance of human Aβ from brain tissue...[and therefore] administration of Aβ peptide has therapeutic benefit in prevention of AD [Alzheimer's disease]". The use of alum as adjuvant is mentioned on page 3, line 23 and in Tables 7 and 8. It is stated that the antigens "include Aβ peptide itself and variants thereof, analogs an mimetic of Aβ peptide that induce and/or crossreact with antibodies to the Aβ peptide", page 13, lines 29-32. Therefore the particular portion of Aβ that was used as antigen would have been a matter of design choice.

It would have been obvious to on of ordinary skill in the art to use a β-amyloid epitope to inhibit the formation of β-amyloid plagues in a human from the teachings of the instant reference, absent convincing proof to the contrary. The vaccine composition of claims 64-78 would have been obvious in view of the teachings of the reference that alum, an adjuvant known to be useful in human, may be used.

It is pointed out that although the instant reference only has 6 days priority on the instant application, it derives priority to two US provisional application the were filed well before the priority date of the instant application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
February 23, 2004